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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,072	07/14/2006	Douglas E. Brough	253625	7914

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EXAMINER
SHEN, WU CHENG WINSTON

ART UNIT	PAPER NUMBER
1632	

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03/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/586,072	**Applicant(s)** BROUGH, DOUGLAS E.	
	Examiner WU-CHENG Winston SHEN	**Art Unit** 1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 February 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☒ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *35, 39-42, 45-48, and 50-53*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Thaian N. Ton/
Primary Examiner, Art Unit 1632

Continuation of 11. does NOT place the application in condition for allowance because: (i) Applicant's arguments have failed to overcome the rejection of claims 35, 39-42, 45-48, and 50-53 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, because Applicant's arguments rely on the proposed claim amendments (deletion of "specifically" in line 6, claim 35), which have not been entered. The rejection is maintained of the record.

(ii) Applicant's arguments have failed to overcome the rejection of claims 35, 39-42, 45-48, and 50-53 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, because Applicant's arguments rely on the proposed claim amendments (deletion of "specifically" in line 6, claim 35), which have not been entered. The rejection is maintained of the record.

With regard to Applicant's arguments regarding the New Matter rejection pertaining to expressing Hath1 from an adenoviral vector belonging to subgroups A, B, D, E, or F, the arguments have been fully considered and found not persuasive because the essence of claimed invention hinges on specifical use of non-subgroup C adenoviral vector in expression of Hath1, thereby, the general statements disclosed in the specification (cited by Applicant on page 6 of Applicant's remarks filed on 02/26/2009) fails to sufficiently describe the claimed invention.

(iii) Applicant's arguments have failed to overcome the scope of enablement rejection of claims 35, 39-42, 45-48, and 50-53 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of changing the sensory perception of an animal, wherein the method comprises administering to the inner ear a pharmaceutical composition comprising an adenoviral vector comprising a nucleic acid sequence encoding an atonal-associated factor Math1 (also known as Hath1 and Atoh1) operably linked to a promoter that drives gene expression in supporting cells of the ear, wherein the nucleic acid sequence is expressed to produce Math1 in supporting cells of the inner ear resulting in generation of sensory hair cells that allow perception of stimuli in the inner ear, does not reasonably provide enablement for an adenoviral vector that expresses any atonal-associated factor other than Math1 driven by a tissue specific promoter that drives expression specifically in the supporting cells of the inner ear, BECAUSE Applicant's arguments rely on the proposed claim amendments (deletion of "specifically" in line 6, claim 35), which have not been entered. The rejection is maintained of the record.

(iv) Applicant's arguments have failed to overcome the rejection of claims 35, 39, 40, 50, and 51 under 35 U.S.C. 103(a) as being unpatentable over Zoghbi et al. (US patent 6,838,444, issued Jan. 4, 2005) in view of Falck-Pedersen et al. (US patent 5,837,511, issued Nov. 17, 1998; this reference is listed as reference #AJ in the IDS filed on 11/16/2006), because Applicant's arguments have been fully considered and found not persuasive.

Applicant's argues that there is no suggestion to combine the cited references and that it is unexpected subgroup B and subgroup D adenoviral vectors enhance delivery of gene of interest to sensory of inner cells (pages 9-10 of Applicant's remarks filed on 02/26/2009).

In response, the Examiner notes that, as stated in the maintained rejection on pages 14-17 of the Final office action mailed on 10/28/2008). It would have been obvious to one of ordinary skill in the art to combine the method of generating hair cells by delivering nucleic acid encoding an atonal associated factor to the inner ear of a subject as taught by Zoghbi et al. using the adenoviral vector belonging to subgroup A, B, D, E, or F to circumvent host immunity taught by the teachings of Falck-Pedersen et al. because the presence of immune response to subgroup C adenovirus prevent efficacious adenovirus vector administration in vivo. As such, the ordinary artisan would have been motivated to use the adenoviral vector belonging to subgroup A, B, D, E, or F to deliver nucleic acid sequence encoding Hath1 in vivo because its effectiveness in expressing the gene of interest in vivo without provoking undesired host immunity to the adenoviral vector. The level of skill in art of molecular cloning is high. Absent evidence from the contrary, one of ordinary skill in the art would have reasonable expectation of success to replace the native coat protein with an engineered coat protein in an adenoviral vector of subgroup A, B, D, E, or F, and deliver it to inner ear to generate sensory hair cells. Therefore, the claimed invention would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

With regard to the asserted requirement for teaching, suggestion, or motivation to render obviousness, the Examiner would like to direct Applicant's attention to recent decision by U.S. Supreme Court in KSR International Co. v. Teleflex, Inc. that forecloses the argument that a specific teaching, suggestion, or motivation is an absolute requirement to support a finding of obviousness. See recent Board decision Ex parte Smith, --USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing KSR, 82 USPQ2d at 1936) (available at http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf).

Furthermore, Applicant's arguments fail to provide any convincing evidence why the observation that subgroup B and subgroup D adenoviral vectors work better than subgroup C adenoviral vector does in transducing inner ear cells is unexpected.

(v) Applicant's arguments have failed to overcome the rejection of Claims 41 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zoghbi et al. (US patent 6,838,444, issued Jan. 4, 2005), in view of Falck-Pedersen et al. (US patent 5,837,511, issued Nov. 17, 1998; this reference is listed as reference #AJ in the IDS filed on 11/16/2006) as applied to claims 35, 39, 40, 50, and 51 above, and further in view of Kovesdi et al. (US patent 6,821,775, issue date, Nov. 23, 2004), because Applicant's arguments have been fully considered and found not persuasive. See above statements in response to the arguments pertaining to the rejection of claims 35, 39, 40, 50, and 51 under 35 U.S.C. 103(a) as being unpatentable over Zoghbi et al. in view of Falck-Pedersen et al.

(vi) Applicant's arguments have failed to overcome the rejection of Claims 45-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zoghbi et al. (US patent 6,838,444, issued Jan. 4, 2005) in view of Falck-Pedersen et al. (US patent 5,837,511, issued Nov. 17, 1998; this reference is listed as reference #AJ in the IDS filed on 11/16/2006) as applied to claims 35, 39, 40, 50, and 51 above, and further in view of Staecker et al. (Staecker et al., Brain-derived neurotrophic factor gene therapy prevents spiral ganglion degeneration after hair cell loss. Otolaryngol Head Neck Surg. 119(1): 7-13, 1998; listed as reference EU on the IDS filed by Applicant on 11/16/2006), because

Applicant's arguments have been fully considered and found not persuasive. See above statements in response to the arguments pertaining to the rejection of claims 35, 39, 40, 50, and 51 under 35 U.S.C. 103(a) as being unpatentable over Zoghbi et al. in view of Falck-Pedersen et al. .